



ISO 9000

Lesson 5 Documentation

Prepared for NASA
by OPM and BDM Federal, Inc.

August 1997

Student Notes:

As mentioned earlier, poor documentation and documentation control are the number one reason for non-certification and have been number one since the inception of ISO 9000. For this reason, a separate section has been dedicated to documentation in this training module.



- ISO 10013, “Guidelines for Developing Quality Manuals”
- Quality System Requirement 4.5 in ISO 9001
- Terms
 - Quality Manual
 - Procedures
 - Work Instructions

Student Notes:

ISO 10013 is a short document discussing the Quality Manual and the relationships of the quality manual, procedures, and work instructions.

Documentation (concluded)

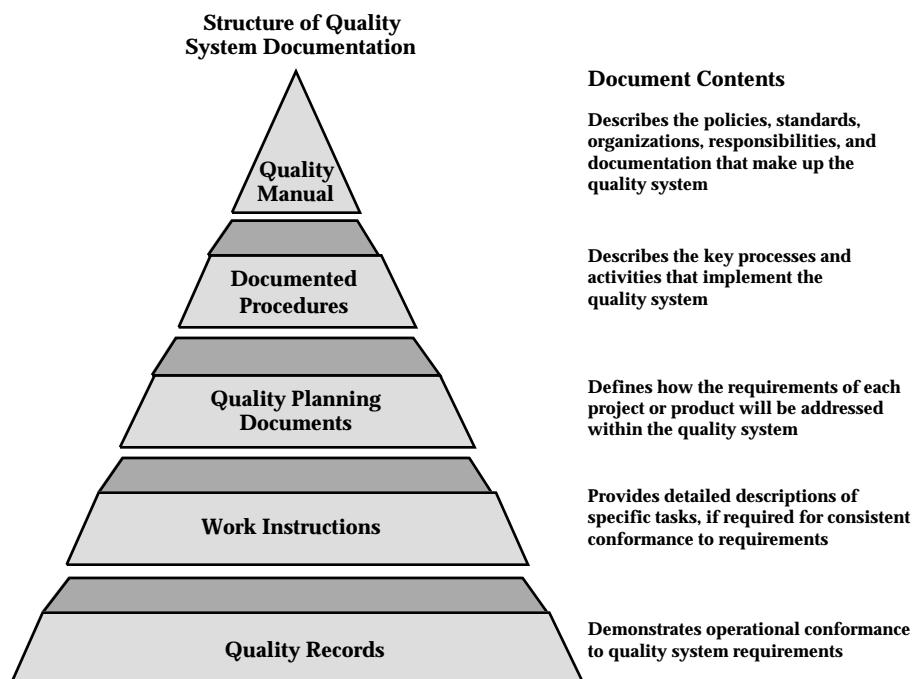


- **Three or Four Tiers**
 - **Quality Manual**
 - **Procedures**
 - **Work Instructions**
 - **Forms and Records**

Student Notes:

The Quality Manual usually parallels ISO9001 in format and content. The manual states that the supplier is complying with each of the 20 elements (which apply). It may contain or may reference procedures that describe how activities are to be coordinated and communicated. These procedures will often, in turn, refer to work instructions that detail the activities. All levels or tiers could be included in the quality manual; however, this leads to a cumbersome volume that is somewhat difficult to keep updated. Keeping the tiers separate greatly facilitates revision and control.

Hierarchy of Documentation



The Quality Manual



- **Explains How Compliance with the 20 Quality System Requirements Is to Be Accomplished**
- **Refers to Procedures and/or Work Instructions**
- **Must Explain Non-Inclusion of any Element**

Student Notes:

Justification must be given for not including any of the 20 elements in the Quality Manual.

If work instructions, procedures, and the quality manual are kept separate, it greatly facilitates revision and update of the documentation. For instance, if procedures and work instructions are made a part of the quality manual, every time a work instruction is revised, the entire manual must be re-issued.

Quality Manual Purpose



- **Establishing and Communicating Policy, Procedures, and Requirements**
- **Implementing the Quality System**
- **Control of Practices and Facilitating Assurance**
- **Documented Bases for Audits**
- **Training Personnel in Quality System**
- **Presentation for External Purposes**
- **Demonstrating Compliance with Standards**

Student Notes:

The quality manual should be the ultimate reference on questions pertaining to any operations affecting quality. As such, it becomes a major element in the management of the organization.

Quality Manual Structure



- **No Required Structure**
- **Contents Should be:**
 - Clear
 - Accurate
 - Complete
 - Stated Simply and Concisely
- **May Only Reference Procedures or May Be a Compilation of Procedures**

Student Notes:

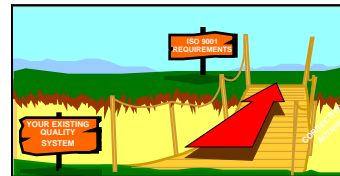
If constructed properly, the quality manual is a great aid to the management of the organization. If complete, there should be no questions as to the course of action to take in any situation concerning quality.

If reference is made to industry or Government standards, these standards must be available at the site of use (ASTM, SAE. etc.).

Developing Documentation



- Perform “Gap” Analysis
 - Determine What Documentation Exists, What Must Be Revised, and What Must Be Developed
 - Decide What Existing Documentation Applies to the ISO Standard
 - Obtain Data about Current System from Users
 - Determine Format and Structure for Intended Manual
 - Classify Existing Documentation with Intended Format and Structure
 - Avoid Excessive Volume by Referencing
 - Construct Manual
 - Final Review
 - Issue



Student Notes:

The quality manual should be written and compiled by senior and middle management. Procedures and work instructions should be developed by the personnel who will use them. Experience has shown that work instructions developed by technical or management personnel are rarely accepted by the workers performing the tasks.

Careful consideration of the above comments, along with critical review of all documentation up front, will save countless hours of revising and adjusting.